STANDARD Table

T-CM04: Concomitant Medication by Generic Name

VERSION 2.0

| TABLE 14.1\_\_x.x  Concomitant Medication by Generic Name  (Analysis Population) | | | | | |
| --- | --- | --- | --- | --- | --- |
|  | | -------------- Test Treatment ---------------- | | |  |
| Generic Name (WHO Q1\_yyyy) | Control  (N=x)  n (%) | Arm 1  (N=x)  n (%) | Arm 2  (N=x)  n (%) | Total  (N=x)  n (%) | Total  (N=x)  n (%) |
|  |  |  |  |  |  |
| Any concomitant medication | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
|  |  |  |  |  |  |
| Generic name 1 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Generic name 2 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Generic name 3 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Generic name ... | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
|  |  |  |  |  |  |
| Note: This table includes all medications administered during the treatment period. Subjects are counted once in each row,  regardless of the number of medications they may have taken. | | | | | |

# Study-Specific Text (to be supplied by Statistician unless otherwise noted)

Analysis Population:

Full Analysis Set

Intent to Treat Population

Safety Analysis Set

Safety Population

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Treatment Groups

Control \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Control … \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Test Treatment Arm 1 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Test Treatment Arm 2 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Test Treatment Arm … \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

WHO Drug Dictionary Version: Obtain from data. Change year only, as AbbVie gets one update annually, in Q1. If a different schedule is followed, change Q1 to the appropriate quarter number.

Generic name: Obtain from data

# Optional Columns and Rows

Total (T1)

Active Total (T2)

# Version History

|  |  |  |
| --- | --- | --- |
| **Version** | **Description** | **Effective Date** |
| 1.0 | Initial version describing how to add functionality to standard TLF shells |  |
| 2.0 | Updated Analysis Population options for consistency across all tables  Updated Test Drug to Test Treatment as referenced in eCRF standard |  |